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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/882,363	06/15/2001	Eugene J. Alexander	STAN-144/01US	6739

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IMAGING THERAPEUTICS, INC.
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EXAMINER

FOREMAN, JONATHAN M

ART UNIT	PAPER NUMBER
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3736

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DATE MAILED: 03/31/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/882,363

Applicant(s)

ALEXANDER ET AL.

Examiner

Jonathan ML Foreman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 January 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 36-43, 45-47, 49, 51, 52 and 54-68 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 57-60 is/are allowed.
- 6) ☒ Claim(s) 36, 42, 43, 45-47, 49, 51, 52, 54-56 and 61-68 is/are rejected.
- 7) ☐ Claim(s) 37-41 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 June 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 18. 6) ☐ Other: _____

DETAILED ACTION

The following Office Action contains rejections to previously allowed and/or previously objected-to-as-allowable material as indicated in Office Action mailed 10/8/03. Accordingly, the following action has been made Non-Final.

Information Disclosure Statement

The information disclosure statement filed 1/9/04 complies with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609. It has been placed in the application file, and the information referred to therein has been considered by the examiner as to the merits.

Drawings

The subject matter shown in figures 9A – 9C, 14A, 14B, 15A, 15B and 18A admits of illustration by drawing; a photograph is not the only practicable medium for illustrating the claimed invention. Drawings must be provided in place of the above-mentioned photographs (MPEP 608.02 “Black and White Photographs”). No new matter is to be added.

Applicant is required to submit a proposed drawing correction in reply to this Office action. However, formal correction of the noted defect may be deferred until after the examiner has considered the proposed drawing correction. Failure to timely submit the proposed drawing correction will result in the abandonment of the application.

Specification

The disclosure is objected to because of the following informalities: Figures 3A, 3B, 11B, 12A, 12B, 14A, 14B, 15A, 15B, 16A – 16C and 17A – 17 C should be described in the “Description of the Drawings”.

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is

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required: Claim 1 uses the phrase “living mammal” in lines 1 – 2. The specification fails to provide proper antecedent basis for this limitation.

Appropriate correction is required.

Claim Objections

Claims 40 and 47 are objected to because of the following informalities: Claim 40, line 3 states “the cartilage defect” without properly first setting forth this limitation. The examiner suggest replacing “the cartilage defect” in line 3 with “a cartilage defect”. Claim 47, line 2 has a misspelled word, “fournier”.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 36, 42, 43, 61 and 64 are rejected under 35 U.S.C. 102(a) as being anticipated by Eckstein et al.

In regards to claims 36, 42, 43, 61 and 64, Eckstein et al. discloses assessing the change of cartilage in a living human knee joint including determining the thickness or volume of a region of cartilage at an initial time and a later time; determining the change in thickness or volume of the cartilage between the initial and later time (Page 597, Col. 1, 1st complete paragraph); electronically transferring an electronically generated image from a transferring device to a receiving device located distant the transferring device, receiving the transferred image at a distant location; and converting the transferred image to a degeneration pattern (Page 594, “Digital Image Processing”).

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Claims 49, 51 and 52 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,320,102 to Paul et al.

In regards to claims 49, 51 and 52, Paul et al. discloses making a three-dimensional map of joint cartilage (Col.4, lines 31 – 34; Col. 5, lines 28 – 32) of a human knee joint including measuring a detectable biochemical component; mapping the amounts of the biochemical component in three dimensions (Col.4, lines 31 – 34; Col. 5, lines 28 – 32; Col. 10, lines 40 - 64); determining the relative amounts of the biochemical component and determining abnormal joint cartilage by identifying the areas having altered amounts of the biochemical component present (Col. 11, lines 27 – 42).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 45 – 47 and 65 – 68 are rejected under 35 U.S.C. 103(a) as being unpatentable over Eckstein et al. in view of U.S. Patent No. 5,427,099 to Adams.

In regards to claims 45 – 47, 65 and 68, Eckstein et al. discloses assessing the change of cartilage in a living human knee joint including determining the thickness or volume of a region of cartilage at an initial time and a later time using a magnetic imaging technique (MRI); determining the change in thickness or volume of the cartilage between the initial and later time (Page 597, Col. 1, 1st complete paragraph). The MRI technique disclosed by Eckstein et al. creates a three-dimensional image which inherently involves first obtaining a series of two-dimensional views that are integrated to create the three-dimensional image. Eckstein et al. discloses the MRI technique

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employing a gradient echo, spin echo, fast-spin echo, driven equilibrium forier transform, spoiled gradient echo or steady state free precession technique (Page 594, "Subjects and Methods").

However, Eckstein et al. fails to disclose placing external markers on the skin overlying the bone on either side of the joint. Adams discloses a marker for use with an MRI to be placed on the skin of an area of interest (Col. 3, lines 44 – 52). It would have been obvious to one having ordinary skill in the art to modify the method as disclosed by Eckstein et al. to include the step of applying a marker or markers as taught by Adams on either side of the joint locate the area of concern, allowing for a narrower focus in the MRI (Col. 3, lines 52 – 57).

In regards to claims 66 and 67, Eckstein et al. in view of Adams discloses determining the thickness or volume of cartilage and determining a change in thickness or volume of cartilage (Page 597, Col. 1, 1st complete paragraph). However, Eckstein et al. in view of Adams fails to disclose determining the width or area of cartilage or determining the change in width or area of cartilage. However, it is well known in the art that width and area of cartilage are desirable measurements commonly made using MRI imaging. It would have been obvious to one having ordinary skill in the art to modify the method as disclosed by Eckstein et al. in view of Adams to include the step of measuring and determining the change in width or area of cartilage if desired.

Claims 54 – 56 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,320,102 to Paul et al. as applied to claim 49 above, and further in view of U.S. Patent No. 5,427,099 to Adams.

In regards to claims 54 – 56, Paul et al. discloses an MRI technique to create a three-dimensional image which inherently involves first obtaining a series of two-dimensional views that are integrated to create the three-dimensional image. Paul et al. discloses the MRI technique employing a gradient echo, spin echo, fast-spin echo, driven equilibrium forier transform, spoiled

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gradient echo or steady state free precession technique (Page 594. "Subjects and Methods").

However, Paul et al. fails to disclose placing external markers on the skin overlying the bone on either side of the joint. Adams discloses a marker for use with an MRI to be placed on the skin of an area of interest (Col. 3, lines 44 – 52). It would have been obvious to one having ordinary skill in the art to modify the method as disclosed by Paul et al. to include the step of applying a marker or markers as taught by Adams on either side of the joint locate the area of concern, allowing for a narrower focus in the MRI (Col. 3, lines 52 – 57).

Claims 62 and 63 are rejected under 35 U.S.C. 103(a) as being unpatentable over Eckstein et al.

In regards to claims 62 and 63, Eckstein et al. discloses determining the thickness or volume of cartilage and determining a change in thickness or volume of cartilage (Page 597, Col. 1, 1st complete paragraph). However, Eckstein et al fails to disclose determining the width or area of cartilage or determining the change in width or area of cartilage. However, it is well known in the art that width and area of cartilage are desirable measurements commonly made using MRI imaging. It would have been obvious to one having ordinary skill in the art to modify the method as disclosed by Eckstein et al to include the step of measuring and determining the change in width or area of cartilage if desired.

Allowable Subject Matter

Claims 57 – 59 are allowed. Claims 37 – 41 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

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Response to Arguments

Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

Conclusion


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jonathan ML Foreman whose telephone number is (703) 305-5390. The examiner can normally be reached on Monday - Friday 8:00 am - 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mary Beth Jones can be reached on (703) 308-3400. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9306 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.



JMLF
March 22, 2004


Acting SPC
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